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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,423	03/23/2004	Thomas P. Jerussi	4821-536-999	2257
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JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017				
EXAMINER				
KAROL, JODY LYNN				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/806,423

Applicant(s)

JERUSSI ET AL.

Examiner

JODY L. KAROL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-63 and 67-94 is/are pending in the application.
- 4a) Of the above claim(s) 61-63, 67-91, 93 and 94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/06)
Paper No(s)/Mail Date 3/23/2004, 1/18/2006, and 2/29/2008.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of Application No. 10/222815 which is a divisional of Application No. 10/014592 which is a divisional of Application No. 09/450690 which claims priority from Provisional Application No. 60/110488. Claims 61-63 and 67-94 are currently pending.

Election/Restrictions

1. Applicant's election **without** traverse of Group II claims 76-82 and 91-94 directed to methods of treatment and election of species **without** traverse of (-)-O-desmethylenlafaxine hydrochloride and anxiety in the reply filed on 12/6/2007 is acknowledged.

Claims 61-36, 67-91, and 93-94 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Accordingly, claim 92 is examined on the merits herein.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4 and 10-15 of U.S. Patent No. 6,911,479 B2 to Jerussi et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to methods of treatment of anxiety comprising administering to a patient in need thereof an effective amount of pharmaceutically acceptable of (-)-O-desmethylvenlafaxine. While the '479 patent does not explicitly claim the hydrochloric salt, its disclosure defines pharmaceutically acceptable salts as salts prepared from non-toxic acids, such as hydrochloric acid (see column 4, lines 35-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, to use the hydrochloric salt of (-)-O-desmethylvenlafaxine in the methods claimed by the '479 patent.

3. Claim 92 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 12, 14-16, and 61 of copending Application No. 11/091,581. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are directed to

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methods of treating anxiety comprising administering to a patient a salt of (-)-O-desmethylvenlafaxine.

The '581 pending claims differ from the instant claims in that they claim the succinate salt of the racemate of O-desmethylvenlafaxine instead of the hydrochloric salt of the optically pure (-) enantiomer of O-desmethylvenlafaxine.

However, absent some difference in kind between the various isomers the skilled artisan would have seen each isomer as *prima facie* obvious (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)). The skilled artisan would have expected optical isomers to be separable and isomers so separated to exhibit physiological effects at varying levels. Possessing a compound known to contain chiral centers, places all the resultant compounds in the skilled artisan's possession. As admitted on the record, O-desmethylvenlafaxine is taught by the co-pending application as optically active. Thus, use of one or another optical isomer by the skilled artisan would have seen as *prima facie* obvious, absent some difference in kind between the various isomers (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)).

It is well settled patent law that optical isomers would have been expected to possess different therapeutic activities. Most biological systems are sensitive to optical isomerism, motivating the skilled artisan to expect one or another optical isomer to effect greater, or lesser physiological activity.

Absence a showing of unexpected results, the hydrochloric salt and the succinate salt of (-)-O-desmethylvenlafaxine are expected to behave similarly in the treatment of anxiety.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph et al. (EP 0 639 374 A2).

Claim 92 is directed to a method of treating a patient suffering from anxiety comprising providing to a patient in need thereof an effective amount of (-)-O-desmethylvenlafaxine hydrochloride.

Rudolph et al. teaches use of 1-[2-dimethylamino)-2-(hydroxyphenyl)ethyl]-cyclohexanol (O-desmethylvenlafaxine) or pharmaceutically acceptable salt thereof for the treatment of anxiety (see abstract, page 8, lines 47-49 and pages 8-9, claims 1-2 and 5). Rudolph et al. further teaches that use of venlafaxine analogs (i.e. O-desmethylvenlafaxine) includes racemates and the individual enantiomers (see page 3, lines 7-10) and that pharmaceutically acceptable salt forms include hydrochloric acids (see page 5, lines 54-57).

Rudolph et al. does not explicitly teach a method of treating anxiety with the (-) enantiomer of O-desmethylvenlafaxine.

However, as stated above, the Examiner cited prior art teaches O-desmethylvenlafaxine as a racemic mixture, placing the skilled artisan in possession of both optical isomers. Absent some difference in kind between the various isomers the skilled artisan would have seen each isomer as *prima facie* obvious (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)). The skilled artisan would have expected optical isomers to be separable and isomers so separated to exhibit physiological effects at varying levels. Possessing a compound known to contain chiral centers,

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places all the resultant compounds in the skilled artisan's possession. Therefore, it would follow that the instant claims recite *prima facie* obvious subject matter and are properly rejected under 35 USC 103. As admitted on the record, O-desmethylvenlafaxine is taught by the Examiner cited prior art as optically active. Thus, use of one or another optical isomer by the skilled artisan would have seen as *prima facie* obvious, absent some difference in kind between the various isomers (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)).

It is well settled patent law that optical isomers would have been expected to possess different therapeutic activities. Most biological systems are sensitive to optical isomerism, motivating the skilled artisan to expect one or another optical isomer to effect greater, or lesser physiological activity.

Thus, the invention as a whole would have been *prima facie* obvious to one skilled in the art at the time it was made.

Conclusion

No claims are allowed.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JODY L. KAROL whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/San-ming Hui/
Primary Examiner, Art Unit 1617